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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,395	04/02/2001	J. Milton Harris	44646/214160	1903

826 7590 03/12/2002

ALSTON & BIRD LLP  
BANK OF AMERICA PLAZA  
101 SOUTH TRYON STREET, SUITE 4000  
CHARLOTTE, NC 28280-4000

EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/824395

Applicant(s)

Harris et al

Examiner

Naff

Group Art Unit

1657

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 12/21/01
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-2/ is/are pending in the application.
- Of the above claim(s) 1, 3 + 8-21 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 2 + 4-7 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

In a response of 12/21/01 to a restriction requirement of 6/22/01, applicants elected without traverse the Group II claims 2-7 and 12-16, and the species of claim 2 for which claims 4-7 are generic.

Claims 1, 8-11 and 17-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 7 (filed 12/21/01).

Claim 3 and 12-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 7.

Claims examined on the merits are 2 and 4-7.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

15 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al (document 17 on form PTO-1449 of 4/2/01) in view of Greenwald et al (5,840,900).

The claims are drawn to a heterobifunctional acrylate of  
5 poly(alkylene oxide) having in the backbone a linkage that is hydrolytically degradable.

Yang et al discloses a heterobifunctional poly(ethylene glycol) having an acrylate group on one terminus and an activated carboxylic acid on the second terminus, and attaching this PEG derivative to a protein.

10 Greenwald et al disclose a prodrug composition containing a hydrolyzable linkage such as an ester linkage between a polymer portion and a biologically active moiety for release of the biologically active moiety (paragraph bridging cols 4 and 5). The polymer may be PEG-acid or PEG-diacid having the hydrolyzable linkage (col 7, lines 1-15 and col 12,  
15 lines 20-61).

It would have been obvious to provide a hydrolyzable linkage in the backbone of the heterobifunctional poly(ethylene glycol) of Yang et al to obtain the function of the linkage to enable releasing a biologically active moiety attached to the heterobifunctional poly(ethylene glycol) as  
20 suggested by Greenwald et al using PEG containing a hydrolyzable linkage for release of an attached biologically active moiety. The modifications required by claims 4-7 would have been matters of obvious choice within the skill of the art in view of Yang et al and Greenwald et al.

Any inquiry concerning this communication or earlier communications  
25 from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on

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Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

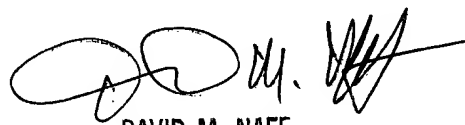
5 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 305-3014 or 308-4242.

10 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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DMN  
3/8/02

  
DAVID M. NAFF  
PRIMARY EXAMINER  
ART UNIT 12851